4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2021-N-1348]

RIN 0910-AI59

Administrative Destruction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing a regulation to implement its new authority to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (FD&C Act), by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction. Once finalized, this regulation will allow FDA to better protect the public health by preventing re-importation and deterring future shipments of refused devices subject to administrative destruction. We also discuss in this Notice of Proposed Rulemaking our intent to change FDA's procedures for administrative destruction of drugs and, if this proposed rule is finalized, these procedures will also include devices subject to administrative destruction. We described our current procedures in the proposed and final rules entitled "Administrative Destruction of Certain Drugs Refused Admission to the United States."

DATES: Either electronic or written comments on the proposed rule must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will

accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-1348 for "Administrative Destruction." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4375, Silver Spring, MD 20993-0002, 301-796-3324.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

The proposed rule would provide to an owner or consignee notice and an opportunity to present testimony when the Agency intends to administratively destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States. The Safeguarding Therapeutics Act (STA) (Pub. L. 116-304), signed into law on January 5, 2021, amended section 801(a) of the FD&C Act (21 U.S.C. 381(a)) to provide FDA with the authority to administratively destroy certain refused devices without providing the owner or consignee with the opportunity for export. FDA proposes to amend § 1.94 (21 CFR 1.94) to provide to the owner or consignee of a refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) notice and an opportunity to present testimony to the Agency prior to destruction of the device.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would provide to an owner or consignee notice and an opportunity to present testimony when the Agency intends to administratively destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States under section 801(a) of the FD&C Act.

FDA proposes to amend part 1 (21 CFR part 1) by expanding the scope of § 1.94, which provides notice and opportunity to present testimony to the owner or consignee prior to the refusal and destruction of certain refused drugs, to also include notice and opportunity to present testimony prior to the refusal and destruction of certain refused devices.

C. Legal Authority

The legal authority for this proposed rule includes sections 701 and 801 of the FD&C Act (21 U.S.C. 371 and 381).

D. Costs and Benefits

The primary public health benefit of the proposed rule, if finalized, would be the value of preventing additional illnesses or deaths by destroying, rather than returning, refused devices valued at $2,500 or less, which may pose a public health risk. This benefit would accrue whenever FDA's existing enforcement tools would not have prevented the violative device from entering the U.S. market. The estimated primary costs of the proposed rule include the additional costs to destroy, rather than return, refused devices valued at $2,500 or less, and the additional costs to store these devices at International Mail Facilities (IMFs) prior to destruction. There would also be one-time costs to FDA to update its electronic Operational and Administrative System for Import Support (OASIS) and System for Entry Review and Import Operations (SERIO); revise its Regulatory Procedures Manual (RPM), Investigations Operations Manual (IOM), and additional FDA and inter-Agency operational procedures; and train employees on the new procedures. Express couriers would incur one-time costs to read and understand the rule. We estimate that the annualized benefits over 10 years would range from $186,000 to $941,000 at a 7 percent discount rate and a 3 percent discount rate, with a primary estimate of $397,000. The annualized costs would range from $69,000 to $1.48 million at a 7 percent discount rate, with a primary estimate of $454,000, and from $65,000 to $1.47 million at a 3 percent discount rate, with a primary estimate of $450,000.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/Acronym	What It Means
Agency	U.S. Food and Drug Administration
CBP	U.S. Customs and Border Protection
CDC	U.S. Centers for Disease Control and Prevention
COVID-19	Disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
FDA	U.S. Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
FD&C Act	Federal Food, Drug, and Cosmetic Act

NIOSH	National Institute for Occupational Safety and Health
OASIS	FDA's Operational and Administrative System for Import Support
SERIO	FDA's System for Entry Review and Import Operations
STA	Safeguarding Therapeutics Act
USPS	United States Postal Service
We, Our, Us	U.S. Food and Drug Administration

III. Background

A. Introduction/History of the Rulemaking

Section 708 in the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), enacted in 2012, gave FDA the authority to destroy, without providing an opportunity for export, any refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) in section 801(a) of the FD&C Act. To implement that authority, FDA published a final rule in the *Federal Register* on September 15, 2015 (80 FR 55237) that revised § 1.94 to provide notice and an opportunity for the owner or consignee to appear before the Agency and introduce testimony prior to the destruction of their drug. Section 801(a) of the FD&C Act further stated that this process may be combined with the notice and opportunity to introduce testimony on the admissibility of the drug under section 801(a) of the FD&C Act, provided appropriate notice is provided to the owner or consignee.

The STA expanded FDA's administrative destruction authority to include any refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). To implement this authority, the proposed rule would amend § 1.94 to provide to the owner or consignee of any refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) notice and an opportunity to appear and introduce testimony prior to the destruction.

B. Need for the Regulation

FDA has refused devices, valued at $2,500 or less, sent to the United States via international mail or express couriers, including illegal devices that are being imported to diagnose, prevent, or treat COVID-19 such as test kits, respirators, and face masks. Other

devices that pose significant public health concerns if counterfeit, unapproved, or unauthorized, or otherwise misbranded or adulterated include contact lenses and blood glucose test strips.

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) issued, pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS (Ref. 1). Additionally, on February 4, 2020, the Secretary of HHS determined, pursuant to section 564 of the FD&C Act (21 U.S.C. 360bbb-3), that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the novel (new) coronavirus first detected in Wuhan City, Hubei Province, China in 2019 (85 FR 7316). The virus is named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the disease COVID-19.

Based on this determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of certain devices (85 FR 17335). On March 11, 2020, the World Health Organization declared the SARS-CoV-2 outbreak to be a pandemic. Since these events, numerous individuals and entities have tried to profit from the pandemic by selling unproven and illegally marketed products making claims that their products can be used to treat, diagnose, or prevent COVID-19. FDA is particularly concerned that these deceptive and misleading products might cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It is likely that the products do not do what they claim and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications (Ref. 2). Once COVID-19 reached the United States, FDA received complaints from American consumers ranging from bogus treatments or cures to inappropriately marketed test kits and fake or substandard personal protective equipment (Ref. 3).

In March 2020, FDA launched Operation Quack Hack to leverage Agency expertise and use advanced analytics to protect consumers from fraudulent medical products related to COVID-19. FDA's Operation Quack Hack team had reviewed thousands of websites, social media posts, and online marketplace listings. We issued hundreds of abuse complaints to online marketplaces and domain registrars about fraudulent products related to COVID-19. As of January 2022, the Agency had issued 260 warning letters to sellers of fraudulent COVID-19 products (Ref. 4).

In Fiscal Year (FY) 2021 (October 1, 2020, to September 30, 2021), CBP seized 38,154 unauthorized COVID-19 test kits and just over 35 million counterfeit face masks (Ref. 5). Particularly during a pandemic, timely access to accurate diagnostic tests is important not only for the individual patient, but for the public at large. We have observed numerous unauthorized test kits for COVID-19 being sold online. Some test developers falsely claim that their tests are FDA-approved or authorized. Others have falsely claimed that their serology tests can diagnose COVID-19 or that they are authorized for at-home testing. As of June 1, 2020, Customs and Border Protection (CBP) had seized more than 107,300 unauthorized COVID-19 test kits (Ref. 6).

As of September 2020, FDA had refused admission to more than 470 shipments of test kits offered for import into the United States, representing more than 460,000 tests overall (Ref. 7). Based on internal data, FDA refused more than 408 shipments in FY 2021. We continue to issue Warning Letters and examine shipments of COVID-19 test kits at International Mail Facilities (IMFs) and express couriers, detaining and refusing unapproved or unauthorized, counterfeit, or otherwise adulterated or misbranded test kits.

Consumers using these illegal test kits risk unknowingly spreading SARS-CoV-2 or not getting treated appropriately for COVID-19. Public health risks from use of illegal test kits include:

- further community spread of the disease;

- a delay in the correct diagnosis and initiation of appropriate treatment for the actual cause of the tested individual's illness;
- waste of healthcare resources and additional, unnecessary evaluations based on results from inaccurate tests;
- results from inaccurate tests may lead the tested individual to take fewer precautions against virus exposure. This may increase the individual's risk of infection and may lead them to not seek testing if later infected with SARS-CoV-2, potentially increasing community spread of the disease;
- unnecessary isolation of a tested individual that might limit contact with family or friends or increase contact with other potentially SARS-CoV-2 infected individuals, and limits in their ability to work; and
- misallocation of resources used for surveillance and prevention of COVID-19 (Ref. 8).

From 2020 to 2021, CBP seized more than 34 million counterfeit face masks and respirators, most of them modeled to resemble N95 or KN95 respirators. Around 20 million of those devices were seized in 2021 (Ref. 9). The Centers for Disease Control and Prevention (CDC) has posted warnings about illegal respirators that are falsely represented to be approved by the National Institute for Occupational Safety and Health (NIOSH). These illegal respirators may not be capable of providing appropriate respiratory protection to medical professionals and frontline workers from SARS-CoV-2. When NIOSH becomes aware of marketed illegal respirators or those marketed respirators misrepresenting NIOSH approval, CDC posts these illegal respirators on its website to alert users, purchasers, and manufacturers of the legitimate respirators (Ref. 10). On March 1, 2021, CBP seized 65,280 counterfeit 3M N95 respirators at the IMF in Chicago. The shipment was from Colombia. CBP officers noticed an unfamiliar chemical smell coming from the respirators and grammatical errors on the fake 3M packaging (Ref. 11). In February 2021, more than 108,000 counterfeit N95 masks--marketed using 3M's branding--were seized by CBP in Cincinnati (Ref. 12). In June 2020, CBP seized 10,000 KN-95

respirators that were manufactured in China and shipped from Israel. The respirators appeared to be of poor quality and packaging. The manufacturer was not registered with FDA and did not have an authorization from FDA to market the respirators in the United States (Ref. 13). CBP seized 58,846 counterfeit facemasks in the fall of 2020. More than 17,000 of these facemasks were shipped from Hong Kong (Ref. 14).

The risks posed by counterfeit, unapproved, or unauthorized, or otherwise misbranded or adulterated devices are not, however, limited to devices for COVID-19. An estimated 45 million Americans wear contact lenses (Ref. 15). FDA regulates all contact lenses as prescription devices. Contact lenses sold without a prescription from unlicensed vendors, including online distributors, may be contaminated and/or counterfeit and are not safe to use. Vendors that advertise colored and decorative contact lenses as cosmetics or sell them over the counter without a prescription, are adulterating and misbranding the device in violation of the FD&C Act and are also violating Federal Trade Commission regulations (Ref. 16).

A prescription is needed for contact lenses because an eye doctor (ophthalmologist or optometrist) must measure each eye to properly fit the lenses and evaluate how the patients' eyes respond to contact lens wear. A poor fit can cause serious eye damage, including:

- scratches on the cornea;
- corneal infection (an ulcer or sore on the cornea);
- conjunctivitis (pink eye);
- decreased vision; and
- blindness.

In addition to the risks above, vendors that sell decorative lenses without a prescription may give few or no instructions on how to clean and care for the lenses. Failure to use the proper solution to keep contact lenses clean and moist can lead to infections. Bacterial infections can be extremely rapid, result in corneal ulcers, and cause blindness--sometimes within as little as 24 hours if not diagnosed and treated promptly (Ref. 17).

Chengdu Ai Qin E-commerce Co., Ltd initiated a nationwide recall of 1,362 pairs of colored contact lenses in June 2020. These contact lenses were distributed without FDA approval or clearance. The recalled products were manufactured in August 2018 in China (Ref. 18).

In January 2017, the owner and operator of Candy Color Lenses, a major online retailer of colored contact lenses in the United States, was sentenced to 46 months in prison for running an international operation importing contact lenses from suppliers in China and South Korea that he knew were counterfeit and/or unapproved for sale in the United States. Candy Color Lenses sold the contact lenses over the internet without a prescription to tens of thousands of customers in the United States. In addition to his prison sentence, the owner was ordered to remit $200,000 in restitution and forfeit $1.2 million in proceeds derived from his illegal scheme (Ref. 19).

The owner of All about Ink, a tattoo shop in Pensacola, Florida, pleaded guilty in June 2019 to misdemeanor charges of receipt of adulterated and misbranded contact lenses, and sale of contact lenses without a prescription. In May 2015, law enforcement seized approximately 600 counterfeit contact lenses that were being imported from China by All about Ink. A number of these contact lenses were tested by FDA and contained microbial contamination. We determined that the types of bacteria in the contact lenses could be hazardous. Between July 2015 and October 2015, law enforcement made several undercover purchases of contact lenses from All about Ink. Following the undercover purchases, a Federal search warrant was executed at the tattoo shop and approximately 200 pairs of contact lenses were seized. Samples of the contact lenses purchased by undercover agents and the seized contact lenses were tested by FDA and a number of these lenses contained microbial contamination. A number of the contact lenses were also counterfeit (Ref. 20).

In 2018, 34.2 million people of all ages--or 10.5 percent of the population in the United States--were estimated to have diabetes (Ref. 21). Using a glucose meter to check and monitor blood sugar is a daily part of life for millions of these Americans. Glucose meters and test strips

are devices regulated by FDA. Some consumers purchase preowned or unauthorized test strips online because they are cheaper. These test strips can potentially cause infection or lead to inaccurate test results, which can cause serious harm, including death. If a consumer receives an inaccurate result from a preowned or unauthorized test strip and uses this result as a basis for their treatment, they could take too much medication or not enough medication, potentially leading to serious injury, including death. It is also possible that preowned test strips may contain small amounts of blood from the previous owner, which can put consumers at risk of infection from potential cross-contamination (Ref. 22).

FDA issued a safety communication in April 2019 warning the public against using test strips, including glucose test strips, from a previous owner (preowned) or test strips that are not authorized for sale in the United States (Ref. 23). Certain test strips require review by FDA prior to being marketed in the United States in order to provide a reasonable assurance of safety and effectiveness when the test strips are used as intended. Test strips not authorized for sale in the United States have not been reviewed by FDA and their ability to provide an accurate result is unknown. Unauthorized test strips can also be faulty or of poor quality. When FDA reporting requirements, such as adverse event reporting, are not followed, we may not become aware of product malfunctions or safety issues associated with these test strips.

There is currently little deterrence against sellers shipping illegal devices or re-sending previously refused devices to the United States via international mail or an express courier. Devices that have been refused admission into the United States might be subsequently offered for re-importation by unscrupulous sellers who attempt to circumvent U.S. import regulatory systems. Under the proposed rule, FDA will be better able to deter such shipments by having an administrative mechanism for destroying a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission to the United States.

C. FDA's Current Regulatory Framework

Based on our internal data, the majority of devices subject to administrative destruction come into the United States via an IMF or an express courier (Ref. 24). For international mail shipments, the United States Postal Service (USPS) routes the parcels to CBP. CBP interdicts certain shipments suspected to contain FDA-regulated products and turns the packages over to FDA for examination and determination of admissibility under the laws and regulations enforced by the Agency.

A device that is imported or offered for import is subject to refusal of admission under section 801(a) of the FD&C Act if, among other reasons, it appears to be adulterated or misbranded in violation of section 501 or 502 of the FD&C Act (21 U.S.C. 351 or 352). In accordance with § 1.94, FDA issues a notice of the Agency's intention to refuse a device to the owner or consignee, as defined in 21 CFR 1.83, stating the reasons for the intended refusal. If the article was sent by international mail, FDA generally considers the addressee of that package to be the owner or consignee. The owner or consignee is given an opportunity to appear before the Agency and introduce testimony orally or in writing on why the device should not be refused admission into the United States. Under section 801(b) of the FD&C Act, the owner or consignee can also submit an application to recondition the device to bring it into compliance with the FD&C Act or to render it other than a food, drug, device, or cosmetic. If, after consideration of any testimony submitted at a §1.94 hearing or if no hearing is requested, we determine that the device should be refused admission, the Agency issues a notice of refusal to the owner or consignee.

Devices that have been refused admission into the United States under section 801(a) of the FD&C Act are required to be destroyed by the owner or consignee unless they are exported within 90 days of the date of notice of the refusal. Refused devices that were shipped via international mail are not in the possession of the owner or consignee and currently are returned by FDA to USPS for return to the sender.

Certain illegal devices may also be destroyed if they are seized and condemned under section 304 of the FD&C Act (21 U.S.C. 334) or if they are seized and forfeited under CBP's seizure and forfeiture authority, such as 19 U.S.C. 1595a(c).

IV. Legal Authority

FDA has the legal authority under section 801(a) of the FD&C Act, as amended by the STA, to administratively destroy, without providing opportunity for export, any device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States. A device that is imported or offered for import is subject to refusal of admission under section 801(a) of the FD&C Act if, among other reasons, it appears to be adulterated or misbranded in violation of section 501 or 502 of the FD&C Act.

Section 801(a) of the FD&C Act also directs FDA to issue regulations that provide the owner or consignee of a device designated by the Agency for administrative destruction with notice and an opportunity to introduce testimony to us prior to the destruction of the device. Section 801(a) of the FD&C Act further states that this process may be combined with the notice and opportunity to appear before FDA and introduce testimony on the admissibility of the device under section 801(a) of the FD&C Act, as long as appropriate notice is provided to the owner or consignee.

Section 701(a) of the FD&C Act authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

As used throughout, the term "device" means those articles meeting the definition of device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)), which includes devices intended for human or animal use. Section 201(h) of the FD&C Act defines the term "device," in part, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of a disease or other condition or in the cure, mitigation, treatment, or prevention of a

disease or intended to affect the structure or any function of the body, and that does not achieve its primary intended purposes through chemical action within or on the body of man or other animals or by being metabolized.

V. Description of the Proposed Rule

To implement section 801(a) of the FD&C Act, as amended by the STA, the proposed rule would revise § 1.94 so that the current notice and hearing provisions that apply to the administrative destruction of certain drugs would also apply to the administrative destruction of certain devices. Specifically, the proposed rule would amend § 1.94(a) to provide the owner or consignee of a refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) with notice and an opportunity to present testimony to the Agency prior to destruction of the device. The proposed rule would also amend § 1.94(c) to specify that the notice and hearing for refusal of admission may be combined with the notice and hearing for destruction of the device.

Once the proposed rule is finalized and in effect, FDA may destroy a device that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) if, among other reasons, it is or appears to be adulterated or misbranded. As described above, FDA would provide to the owner or consignee notice and an opportunity to present testimony prior to the administrative destruction of such a device.

VI. FDA Procedures for Administrative Destruction

In the preamble of the proposed rule (79 FR 25758) and the preamble of the final rule (80 FR 55237) for "Administrative Destruction of Certain Drugs Refused Admission to the United States," FDA explained that the Agency intended to exercise its new authority in section 801(a) of the FD&C Act, added by section 708 in FDASIA, by taking the further step of destroying a drug, only in situations where, after providing the owner or consignee with notice and the

opportunity to introduce testimony, the Agency has determined that the drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act.

The Agency intends to make a change to our procedures for destroying a refused drug from what was described in the preambles to the proposed and final rules for the administrative destruction of a drug. Under our revised procedures for destruction, FDA might not make a determination that a drug subject to administrative destruction is, in fact, adulterated, misbranded, counterfeit, or unapproved if the owner or consignee has not requested a hearing to contest the administrative destruction (including the basis for refusal of admission). This means that, if an owner or consignee does not request to present testimony contesting an administrative destruction, FDA might administratively destroy that drug if it appears to be adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act. FDA will continue to make a determination that a drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act when an owner or consignee requests a hearing under §1.94 to contest the administrative destruction (including the basis for refusal of admission).

We intend to use the same procedures for devices that are subject to administrative destruction if this proposed rule is finalized and becomes effective.

At the time of the administrative destruction of refused drugs rulemaking, administrative destruction was a novel program for the Agency. The destruction program for drugs has now been in place at FDA for more than 5 years; it was implemented starting in April 2016. After careful monitoring of the program over that time, we believe that taking the further step of making a determination that a refused drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act is no longer warranted where an owner or consignee has not requested the opportunity to submit testimony to contest the destruction. Since we implemented the program, most (e.g., more than 99 percent in fiscal year 2021 (Ref. 25)) of the drugs valued at $2,500 or less that FDA initially determined to be subject to administrative destruction were later determined by FDA to be, in fact, adulterated, misbranded, or unapproved

in violation of section 505 of the FD&C Act. Additionally, FDA has only received one request from an owner or consignee to introduce testimony to contest FDA's intention to destroy a drug since we implemented the program. Further, we have found that having our import reviewers take the further step of making and documenting a determination that a drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act can double the time it takes to designate a drug for refusal and destruction. Given our experience with the destruction program for drugs, the high volume of illegal drugs being imported via international mail and express couriers, and our limited resources to review drugs for admissibility, we intend to change our administrative destruction procedures as described above.

Comments on these revised procedures for the administrative destruction of certain drugs and devices may be submitted in accordance with the instructions above for submitting comments to this proposed rule.

VII. Proposed Effective Date

FDA intends that the effective date of the new regulatory requirements will be 30 days after publication of a final rule in the *Federal Register*.

VIII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the number of expected destructions per year and the very small value per event, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would implement the authority of FDA to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been offered for import and refused admission into the United States under the FD&C Act, by providing notice and opportunity to the owner or consignee to appear and introduce testimony to FDA prior to the destruction. Because our internal data show that the majority of devices offered for import, valued at $2,500 or less, and refused in FY 2022 were shipped via international mail and express couriers, FDA currently intends to implement the proposed rule, if finalized, at IMFs and express couriers (Ref. 24). We do not, therefore, consider impacts related to shipments via commercial air, land, and seaports.

The costs and benefits of the proposed rule, if finalized, would depend on the number of administrative destructions that FDA orders each year for refused devices valued at $2,500 or less. For our primary estimates, we assume that FDA would order the destruction of 65 percent of refused devices valued at $2,500 or less. We additionally assume that FDA would contract

out the act of destruction to a private firm and combine the notice and hearing process for destruction with the current notice and hearing process for refusal. We summarize the costs and benefits of the proposed rule, if finalized, in table 1.

We estimate that the annualized benefits over 10 years would range from $186,000 to $941,000 at a 7 percent discount rate and a 3 percent discount rate, with a primary estimate of $397,000. The annualized costs would range from $69,000 to $1.48 million at a 7 percent discount rate, with a primary estimate of $454,000, and from $65,000 to $1.47 million at a 3 percent discount rate, with a primary estimate of $450,000.

Over 10 years, the present value of total benefits would range from $1.31 million to $6.61 million at a 7 percent discount rate, with a primary estimate of $2.79 million, and from $1.59 million to $8.03 million at a 3 percent discount rate, with a primary estimate of $3.39 million. The present value of total costs would range from $488,000 to $10.36 million at a 7 percent discount rate, with a primary estimate of $3.19 million, and from $555,000 to $12.54 million at a 3 percent discount rate, with a primary estimate of $3.84 million.

Table 1.--Summary of Benefits, Costs, and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year[1]	$0.397	$0.186	$0.941	2021	7%	10 years	Benefits include cost savings to express couriers and USPS.
		$0.397	$0.186	$0.941	2021	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year[1]	$0.454	$0.069	$1.475	2021	7%	10 years	
		$0.4500	$0.065	$1.470	2021	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized					7%		

	Monetized $millions/year					3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No estimated effect. Small Business: No estimated effect. Wages: No estimated effect. Growth: No estimated effect.							

[1] When calculating annualized benefits and costs, we assume that payments occur at the end of each period.

The primary benefit of the proposed rule, if finalized, would be the value of additional illnesses or deaths averted from destroying, rather than returning, refused devices valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). If a destroyed device is a counterfeit or an otherwise falsified version of an approved or cleared device, the owner of the approved or cleared device may benefit through increased sales, brand value, or research and development funding. The threat of destruction additionally may have a deterrent effect, reducing the amount of adulterated or misbranded (violative) devices that are offered for import into the United States. These benefits would accrue whenever FDA's existing enforcement tools would not have prevented the violative device from entering the U.S. market; the current policy for returning refused devices does not preclude the re-importation of the device into the United States in the future. We do not have enough information to quantify these benefits. Express couriers and the USPS would incur cost savings from returning fewer refused devices to their country of origin (the current procedure for refused devices valued at $2,500 or less).

Quantified costs of the proposed rule, if finalized, would include the costs to FDA to destroy, rather than return, refused devices valued at $2,500 or less, and the additional costs to store these devices at IMFs prior to destruction. FDA would additionally incur one-time costs to update its electronic import systems, OASIS and SERIO; revise the RPM, IOM, and additional FDA and inter-Agency operational procedures; and train employees on the new procedures. Express couriers would incur one-time costs to read and understand the rule.

If our assumptions do not hold, FDA may incur additional costs, including costs to purchase equipment to destroy refused devices, costs to train employees administering the

destruction of refused devices, costs to separately notify the owners or consignees of refused devices, and costs to prepare for hearings on destruction that the owners or consignees of refused devices request.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 25) and at https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

FDA has concluded that the requirements contained in this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)(ii)).

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies

that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*1. Secretary of Health and Human Services Alex M. Azar II. "Determination that a Public Health Emergency Exists." Last reviewed January 31, 2020 (subsequently renewed). https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

*2. FDA. "Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments." Content current as of February 3, 2022. https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments.

*3. Assistant Commissioner for Regulatory Affairs Judy McMeekin and Deputy Commissioner for Medical and Scientific Affairs Anand Shah (hereinafter McMeekin and Shah). "FDA Protects Patients and Consumers from Fraud During COVID-19." Content current as of July 20, 2020. https://www.fda.gov/news-events/fda-voices/fda-protects-patients-and-consumers-fraud-during-covid-19.

*4. FDA. Testimony of Acting Commissioner Janet Woodcock. Accessed July 11, 2022. Addressing New Variants: A Federal Perspective On The Covid-19 Response - 01/11/2022 | FDA

*5. U.S. Customs and Border Protection. CBP Trade and Travel Report. Fiscal Year 2021/April 2022. Accessed July 11, 2022. https://www.cbp.gov/document/annual-report/cbp-trade-and-travel-fiscal-year-2021-report.

6. U.S. Customs and Border Protection. "CBP Continues to Seize Large Number of Counterfeit and Unapproved COVID-19 Products." Released June 5, 2020. Last modified February 3, 2021. https://www.cbp.gov/newsroom/national-media-release/cbp-continues-seize-large-number-counterfeit-and-unapproved-covid-19.

*7. Commissioner of Food and Drugs Stephen M. Hahn, MD. "Testimony, COVID-19: An Update on the Federal Response, September 22, 2020 (Before the Senate Committee on Health, Education, Labor, and Pensions)." Content current as of September 24, 2020. https://www.fda.gov/news-events/congressional-testimony/covid-19-update-federal-response-09232020.

*8. FDA. "Counterfeit At-Home OTC COVID-19 Diagnostic Tests." Content Current as of April 29, 2022. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/counterfeit-home-otc-covid-19-diagnostic-tests; and FDA. "Certain COVID-19 Serology/Antibody Tests Should Not Be Used--Letter to Clinical Laboratory Staff and Health Care Providers." Content current as of June 19, 2020. https://www.fda.gov/medical-devices/letters-health-care-providers/certain-covid-19-serologyantibody-tests-should-not-be-used-letter-clinical-laboratory-staff-and.

9. ABC Action News, Philadelphia. "20 Million Fake Masks Seized Since Beginning of Year, CBP Officials Say." *6ABC*, April 8, 2021. https://6abc.com/fake-covid-masks-cbp-seized-coronavirus-counterfeit/10499964/.

*10. CDC, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory. "Counterfeit Respirators/Misrepresentation of NIOSH-Approval." Last reviewed March 17, 2022. https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.

*11. U.S. Customs and Border Protection. "Over 65K Counterfeit 3M Masks Seized in Chicago." Released and last modified March 5, 2021. https://www.cbp.gov/newsroom/local-media-release/over-65k-counterfeit-3m-masks-seized-chicago.

12. ABC Action News, Philadelphia, *supra* reference 9.

*13. U.S. Customs and Border Protection. "CBP Baltimore Field Office Continues to Seize Unapproved PPE and COVID-19 Medications." Released June 5, 2020. Last modified February 3, 2021. https://www.cbp.gov/newsroom/local-media-release/cbp-baltimore-field-office-continues-seize-unapproved-ppe-and-covid-19.

*14. U.S. Customs and Border Protection. "CBP Baltimore Field Office Seizes nearly 59,000 Counterfeit COVID-19 Facemasks and Other Test Kits and Medications." Released October 7, 2020. Last modified February 3, 2021. https://www.cbp.gov/newsroom/local-media-release/cbp-baltimore-field-office-seizes-nearly-59000-counterfeit-covid-19.

*15. CDC. "Healthy Contact Lens Wear and Care: Fast Facts." Last reviewed December 30, 2021. https://www.cdc.gov/contactlenses/fast-facts.html.

*16. FDA. "Focusing on Contact Lens Safety." Content current as of October 16, 2019. https://www.fda.gov/consumers/consumer-updates/focusing-contact-lens-safety.

*17. FDA. " 'Colored' and Decorative Contact Lenses: A Prescription Is a Must." Content current as of July 31, 2019. https://www.fda.gov/consumers/consumer-updates/colored-and-decorative-contact-lenses-prescription-must.

*18. FDA. "Chengdu Ai Qin E-Commerce Co., Ltd Issues Nationwide Recall of TTDEYE Brand Colored Contact Lenses." Published and content current as of June 24, 2020. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/chengdu-ai-qin-e-

commerce-co-ltd-issues-nationwide-recall-ttdeye-brand-colored-contact-lenses; and FDA. "Enforcement Report, Event 85923." Accessed March 29, 2022. https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=85923.

*19. U.S. Department of Justice. "Owner of Major Online Colored Contact Lens Business Sentenced to 46 Months in Prison in Largest-Ever Scheme to Import and Sell Counterfeit and Misbranded Contact Lenses Prosecuted in the United States." Released and updated January 18, 2017. https://www.justice.gov/opa/pr/owner-major-online-colored-contact-lens-business-sentenced-46-months-prison-largest-ever.

*20. U.S. Department of Justice. "Pensacola Woman Pleads Guilty to Selling Counterfeit Contact Lenses." Released and content current as of October 8, 2019. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/pensacola-woman-pleads-guilty-selling-counterfeit-contact-lenses.

*21. CDC. "National Diabetes Statistics Report: 2020: Estimates of Diabetes and Its Burden in the United States." Accessed March 29, 2022. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

*22. FDA. "The FDA Warns Against Use of Previously Owned Test Strips or Test Strips Not Authorized for Sale in the United States: FDA Safety Communication." Issued April 8, 2019. Content current as of April 8, 2019. https://www.fda.gov/news-events/press-announcements/fda-warns-about-risks-using-home-use-test-strips-are-pre-owned-or-not-authorized-sale-us-including.

*23. Id.

*24. FDA. Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS). 2022 data as of July 12, 2022.

25. FDA. Administrative Destruction: Preliminary--Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2022. https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting, and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is proposed to be amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 379j-31, 381, 382, 384, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

2. In § 1.94 revise paragraphs (a) and (c) to read as follows:

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission or that the article is a drug or device that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

* * * * *

(c) If the article is a drug or device that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director may give the owner or

consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. The division director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

Dated: September 30, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022-21809 Filed: 10/6/2022 8:45 am; Publication Date: 10/7/2022]